

## **REMARKS**

Applicants have received and carefully reviewed the Final Office Action mailed May 11, 2010. Currently, claims 1-40 remain pending of which claims 11-16, 19, 21-24, and 34-40 were previously withdrawn from consideration. Claims 1-10, 17-18, 20, and 25-33 have been rejected. With this Amendment, claims 1, 34, and 36 have been amended. Favorable consideration of the following remarks is respectfully requested.

### ***Interview Summary***

Applicants would like to thank the Examiner for the courtesies extended during the telephonic interview of July 22, 2010 between the Examiner and Applicants' representative Benjamin J. Nyquist. During the interview, claim 1 and the Bleam et al. and Vardi et al. references were discussed. While no agreement was reached, the Examiner indicated that clarifying the outer surface of the rotatable sheath and clarifying that the rotatable sheath is rotatable relative to the catheter would appear to overcome the current rejection, but further consideration would be needed.

### ***Claim Rejections – 35 U.S.C. § 102***

On page 2 of the Final Office Action, claims 1-8, 17-18, and 29-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Bleam et al. (U.S. Patent No. 6,143,016). After careful review, Applicants respectfully disagree.

Turning to claim 1, which recites:

1. A catheter assembly comprising:
  - a catheter, the catheter comprising a catheter shaft;
  - a first rotatable sheath, the first rotatable sheath including a radial outer surface and a radial inner surface, the first rotatable sheath being disposed about and rotatable relative to a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft;
  - a first guidewire housing, the first guidewire housing defining a first guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to the radial outer surface of the first rotatable sheath;

a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing; and

a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being disposed about the catheter shaft adjacent to the first stent.

Nothing in Bleam et al. appear to disclose many elements of claim 1, including for example, “a first rotatable sheath, the first rotatable sheath including a radial outer surface and a radial inner surface, the first rotatable sheath being disposed about and rotatable relative to a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft”, “a first guidewire housing, the first guidewire housing defining a first guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to the radial outer surface of the first rotatable sheath”, or “a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing”.

Instead, Bleam et al. appear to disclose an assembly 10 for deploying stent 12 including a balloon catheter 14 having a catheter shaft 15. The assembly 10 appears to also include a sheath 28 having a distal portion 34 and a proximal portion 36. The distal portion 34 of the sheath 28 appears to include an elastic, expandable material that can be expanded by outward pressure from within sheath 28. The proximal portion 36 appears to be formed of a material to enhance the pushability of the sheath 28. A stent 12 appears to be positioned on the distal portion 34 of the sheath for delivery into the vessel.

In the Final Office Action, the element 14 of Bleam et al., which is a balloon catheter, is cited as teaching the claimed first guidewire housing. However, clearly balloon catheter 14 is not engaged to the radial outer surface of the distal portion 34 of sheath 28, which was cited as the claimed first rotatable sheath. As such, nothing in Bleam et al. appears to disclose “a first guidewire housing, the first guidewire housing defining a first guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to the

radial outer surface of the first rotatable sheath", as recited in claim 1.

As noted in MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In view of the foregoing, Bleam et al. cannot be considered as teaching each and every element or the identical invention as in claim 1. Further, there appears to be no reason to modify the teachings of Bleam et al. to arrive at the claimed catheter assembly. For at least these reasons, claim 1 is believed to be patentable over Bleam et al. For similar reasons and others, claims 2-8, 17-18, and 29-30, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Bleam et al.

On page 3 of the Final Office Action, claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Vardi et al. (U.S. Patent No. 6,692,483). After careful review, Applicants respectfully disagree.

Turning to claim 1, which recites:

1. A catheter assembly comprising:
  - a catheter, the catheter comprising a catheter shaft;
  - a first rotatable sheath, the first rotatable sheath including a radial outer surface and a radial inner surface, the first rotatable sheath being disposed about and rotatable relative to a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft;
  - a first guidewire housing, the first guidewire housing defining a first guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to the radial outer surface of the first rotatable sheath;
  - a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath and at least a portion of the first guidewire housing; and
  - a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being disposed about the catheter shaft adjacent to the first stent.

Nothing in Bleam et al. appear to disclose many elements of claim 1, including for example, “a first rotatable sheath, the first rotatable sheath including a radial outer surface and a radial inner surface, the first rotatable sheath being disposed about and rotatable relative to a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft” or “a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being disposed about the catheter shaft adjacent to the first stent”. For at least these reasons, claim 1 is believed to be patentable over Vardi et al.

***Claim Rejections – 35 U.S.C. § 103***

On page 3 of the Final Office Action, claims 9-10, 20, 25-28, and 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016). On page 4 of the Final Office Action, claims 9-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016) in view of Girton et al. (U.S. Patent No. 6,997,946). On page 5 of the Final Office Action, claims 20 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016) in view of Buigre et al. (U.S. Patent No. 6,391,052). On page 5 of the Final Office Action, claims 26-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016) in view of Trogolo et al. (U.S. Patent No. 6,296,863). On page 6 of the Final Office Action, claims 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bleam et al. (U.S. Patent No. 6,143,016) in view of Suzuki et al. (U.S. Publication No. 2005/0027248). Applicants respectfully disagree. As discussed previously, claim 1 is believed to be patentable over Bleam et al. and nothing in the additional references appear to remedy the noted shortcomings of Bleam et al. For at least these reasons, claims 9-10, 20, 25-28, and 31-33, which depend from claim 1 and include additional distinguishing features, are also believed to be patentable over the cited references.

**Conclusion**

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

Date: \_\_\_\_\_

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